

Appl. No. : 10/005,684
Filed : November 8, 2001

REMARKS

Claims 1, 10 and 11 have been amended and new Claim 12 has been added. As a result, Claims 1-12 remain pending in the present application. Support for the amendments is found in the specification and claims as filed. Accordingly, the amendments do not constitute the addition of new matter. Reconsideration of the application in view of the foregoing amendments and following comments is respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected Claims 1-6 under 35 U.S.C. § 112, second paragraph, as being indefinite.

Regarding Claim 1, the Examiner objected to the preamble for reciting “[a] method of diagnosing the likelihood and severity of autoimmune disease in a patient” while the recited steps are directed to indicating “ongoing pathology or prediction of early pathogenic reaction for autoimmune disease.” As amended, Claim 1 recites, *inter alia*, “[a] method for distinguishing possible autoimmunity from possible cardiovascular disease with autoimmune disease in a patient” which correlates with the subsequent recited steps. Accordingly, the preamble of Claim 1 is clear.

The Examiner also objected to recitation of “recombinant antigens or synthetic peptides in a sample from said patient” in Claim 1 because the Examiner is unclear as to why a patient sample would have recombinant antigens or synthetic peptides. As amended, Claim 1 recites, *inter alia*, “determining a level of a first set of antibodies directed against a plurality of different antigens, and/or corresponding recombinant antigens or synthetic peptides said first set of antibodies being associated with cardiovascular disease in a sample from said patient; and b) determining a level of a second set of antibodies directed against a plurality of different antigens and/or corresponding recombinant antigens or synthetic peptides, said second set of antibodies being associated with autoimmune disease in a sample from said patient.” Accordingly, Claim 1 indicates that the antibodies are measured from the patient sample. These antibodies can be raised against recombinant and synthetic peptides. In particular, these antibodies can bind to

Appl. No. : 10/005,684
Filed : November 8, 2001

recombinant and synthetic peptides that have been bound to a plate for an assay. Support for this explanation can be found in the specification at paragraph [0054] which states that “[t]he test utilizes a highly sensitive and accurate ELISA test method that measures saliva IgA specific antibody titers to the purified antigens or a corresponding antigen or synthetic peptide from autoantigens.” Furthermore, many examples in the specification also support the claim, including Examples 2-8 which describe immobilization of the purified antigens or a corresponding antigen or synthetic peptide from infectious agents to a solid surface. Accordingly, as amended and explained above, Claim 1 is clear and definite.

The Examiner also objected to the term “normal” in Claim 1. The term “normal” is defined in the specification at paragraph [0104] as “an average level of antibody taken from a set of healthy control individuals.” The claim now refers only to “higher than normal levels.” Hence, the results from the assay provide a diagnostic outcome. While it is true that a small number of individuals tested in the results shown in Figure 1 have antibody levels lower than those of healthy controls, this does not mean that the claimed assay does not provide a diagnostic outcome. The patients tested had known risk factors for autoimmune disease. One would expect a small number of those would not, in part, test positive for autoimmune disease. Accordingly, the term “normal” in Claim 1 is clear and definite.

The Examiner objected to the term “immune complexes” in Claim 2. According to the Examiner, the term is unclear as to the type of immune complexes or how the immune complexes correlate to autoimmune disease. The specification at pages 7-8 gives a background to immune complexes’ definition and their role in autoimmune disease. An especially noted section is paragraph [0024] which describes immune complexes. Another especially noted section is paragraph [0025] which discloses that “[b]oth exogenous and endogenous antigens can trigger pathogenic immune responses that result in immune complex (IC) disease. Because circulating IC’s play such an important part in many diseases, including autoimmunity,...the demonstration of IC’s in tissues and biological fluids has achieved rising prominence.” As such, the term “immune complexes” in Claim 2 is clear and definite with respect to defining the type of immune complexes and the correlation of immune complexes to autoimmune disease.

Appl. No. : 10/005,684
Filed : November 8, 2001

The Examiner objected to the limitation that the antibodies bind to SEQ ID NO:7 in Claim 11. The Examiner is unclear if the antibody is only capable of binding to SEQ ID NO:7, or if the antibodies are capable of binding to a plurality of antigens, including SEQ ID NO:7. Example 8 in the specification shows that the antibodies are capable of binding to SEQ ID NO:7 which was synthesized on a peptide synthesizer and, hence, is purified. Amended Claim 11 recites, *inter alia*, “wherein the antibodies can bind to SEQ ID NO:7.” Accordingly, Claim 11 is clear and definite.

With respect to Claims 10 and 11, the Examiner objected to the limitation that the antibodies bind to SEQ ID NO.5, 6, or 7 because the Examiner was unsure if the limitations refer to the capabilities of the antibodies, or if the limitations refer to an actual method step. Like above, Example 8 in the specification shows that the antibodies can bind to SEQ ID NO.5, 6 or 7. Amended Claims 10 and 11 recite, *inter alia*, “wherein the antibodies can bind to SEQ ID NO:5 or SEQ ID NO:6” and “wherein the antibodies can bind to SEQ ID NO:7,” respectively. Accordingly, Claims 10 and 11 are clear and definite.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. § 112, first paragraph

The Examiner rejected Claims 1-6 under 35 U.S.C. § 112, first paragraph, because he believes that the specification is not enabling for a method for diagnosing the likelihood or severity of autoimmune disease, or for prediction of early pathogenic reaction for autoimmune disease. As amended Claim 1 recites, *inter alia*, “[a] method for distinguishing possible autoimmunity from possible cardiovascular disease with autoimmune disease in a patient” which correlates with the subsequent recited steps. The support for this amendment is found in the specification in Figure 6 which shows a table of correlation of reactivity of saliva IgA antibody against infectious agents and autoantigens to medical conditions. The distinguishability of possible autoimmunity from possible cardiovascular disease with autoimmune disease in a patient can be obtained from Figure 6.

Appl. No. : 10/005,684
Filed : November 8, 2001

The Examiner further rejected Claims 1 and 3-9 because the specification is not enabling for a method of detecting antibodies against any and all antigens. As amended, Claim 1 recites, *inter alia*, “determining a level of a first set of antibodies directed against a plurality of different antigens and/or corresponding recombinant antigens or synthetic peptides said first set of antibodies being associated with cardiovascular disease in a sample from said patient” and “determining a level of a second set of antibodies directed against a plurality of different antigens and/or corresponding recombinant antigens or synthetic peptides, said second set of antibodies being associated with autoimmune disease in a sample from said patient” Accordingly, as amended, Claim 1 recites antibodies that are directed against certain antigens which are clearly defined and enabled by the specification.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 102

The Examiner rejected Claims 1-5 and 7-12 under 35 U.S.C. § 102(b) as being anticipated by Roper (U.S. Patent No. 4,753,893). Roper et al. discloses a method of detecting rheumatoid factor and a method of immobilizing circulating immune complexes from fluids for the purpose of detection or removal thereof from body fluids.

The Examiner rejected Claims 1-5 and 7-10 under 35 U.S.C. § 102(b) as being anticipated by Gaynor et al. (U.S. Patent No. 6,001,964). Gaynor et al. discloses a method for identifying a peptide which binds to an anti-double stranded DNA antibody and applies the method to diagnosing and treating systemic lupus erythematosus.

The Examiner rejected Claims 1-6 under 35 U.S.C. § 102(e) as being anticipated by Yeaman (U.S. Patent No. 6,645,725). Yeaman et al. teaches a method for detecting endometriosis in a patient by employing immunoassays which detect autoantibodies in a serum sample which react with Thomsen-Friedenreich antigen (Tf).

Appl. No. : 10/005,684
Filed : November 8, 2001

According to M.P.E.P. 2131.01, “[a] claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference.”

As amended, Claim 1 recites, *inter alia*, “[a] method for distinguishing possible autoimmunity from possible cardiovascular disease with autoimmune disease in a patient” and subsequent steps that correlate with the preamble.

None of the recited references discloses “a method for distinguishing possible autoimmunity from possible cardiovascular disease with autoimmune disease in a patient,” as recited in Claim 1. Indeed, none of the references even mentions cardiovascular disease, much less the distinguishability of possible autoimmunity from possible cardiovascular disease with autoimmune disease. Accordingly, the cited prior art references do not disclose each and every element as set forth in the Claim 1.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 102(b) and 102(e).

Rejections under 35 U.S.C. § 103

The Examiner rejected Claim 11 under 35 U.S.C. § 103(a) as being anticipated by Roper (U.S. Patent No. 4,753,893) in light of Gurney et al. (Gurney et al., Molecular cloning and expression of neuroleukin, a neurotrophic factor for spinal and sensory neurons, 1986, Science, 234 (4776), 566-74). Also, the Examiner rejected Claim 11 under 35 U.S.C. § 103(a) as being anticipated by Gaynor et al. (U.S. Patent No. 6,001,964) in light of Gurney et al. (Gurney et al., Molecular cloning and expression of neuroleukin, a neurotrophic factor for spinal and sensory neurons, 1986, Science, 234 (4776), 566-74).

As stated above, Roper et al. discloses a method of detecting rheumatoid factor and a method of immobilizing circulating immune complexes from fluids for the purpose of detection or removal thereof from body fluids.

Appl. No. : 10/005,684
Filed : November 8, 2001

As stated above, Gaynor et al. discloses a method for identifying a peptide which binds to an anti-double stranded DNA antibody and applies the method to diagnosing and treating systemic lupus erythematosus.

Gurney et al. teaches that IgG and IgM react with neuroleukin, which contains SEQ ID NO.7.

According to M.P.E.P. 2143.03, “[t]o establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.”

Claim 11 is dependent on Claim 1. As amended, Claim 1 recites, *inter alia*, “[a] method for distinguishing possible autoimmunity from possible cardiovascular disease with autoimmune disease in a patient” and subsequent steps that correlate with the preamble.

Along the lines with the above statements, none of the recited references teaches or suggests “a method for distinguishing possible autoimmunity from possible cardiovascular disease with autoimmune disease in a patient,” as recited in Claim 1. Indeed, none of the references even mentions cardiovascular disease, much less the distinguishability of possible autoimmunity from possible cardiovascular disease with autoimmune disease. Accordingly, the cited prior art references do not teach or suggest all the claim limitations of Claim 11.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing amendments and comments, it is respectfully submitted that the present application is fully in condition for allowance, and such action is earnestly solicited.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped

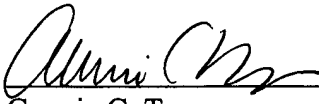
Appl. No. : 10/005,684
Filed : November 8, 2001

issues remain or if any issues require clarification, the Examiner is respectfully requested to call the undersigned in order to resolve such issue promptly.

Respectfully submitted,

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